

Notice of Allowability

Application No.

10/632,413

Examiner

Casey Hagopian

Applicant(s)

RICHARD ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the after-final amendment filed 8/29/2007.
2. ☒ The allowed claim(s) is/are 6, 12-16, 18-23 and 27-35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application
- ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
- ☐ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the prior art does not teach an implantable or insertable medical device comprising a therapeutic agent and a polymeric release region comprising a graft copolymer, said graft copolymer having a) a main chain comprising poly(methyl acrylate), poly(ethyl acrylate) or poly(butyl acrylate) and b) side chains comprising poly(styrene) or poly(methyl methacrylate). Effectively, there are 6 possible graft copolymer combinations that all appear to be free of the art for medical or therapeutic purposes. The prior art also does not teach an implantable or insertable medical device comprising a therapeutic agent and a polymeric release region comprising a graft copolymer, said graft copolymer selected from polyethylacrylate-graft-polystyrene copolymer, polybutylacrylate-graft-polystyrene copolymer and polydimethylsiloxane-graft-polystyrene copolymer.

Chen et al. (US 2003/0039689 A1) teaches a polymer-based, sustained release drug delivery system (title; abstract). Chen specifically exemplifies a coating comprising a random poly(ethyl acrylate and methyl methacrylate) copolymer and 5-fluouracil, an anti-neoplastic drug (example 9). Chen further teaches that the coatings may be applied to medical devices including catheters vascular grafts and stents (paragraphs 0037-0038). Chen is silent to a graft copolymer. One of ordinary skill in the art would not be motivated to alter the random copolymer into a graft copolymer because the change in structure would lead to a drastic change in physical and chemical properties.

Siol et al. (USPN 5,266,645) teaches acrylate-methacrylate graft polymerizates. Siol teaches that grafting methyl methacrylate on preformed polyethylacrylate was

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deemed unsuccessful because the properties of the graft copolymer were only satisfactory (col. 3, lines 39-51). Additionally, Siol is silent to medical device and therapeutic agents. One of ordinary skill in the art would not have been motivated to attempt to graft methyl methacrylate to polyethylacrylate because Siol teaches that the properties of the resulting copolymer are undesirable.

For these reasons, it would not have been obvious for one of ordinary skill in the art to make the necessary alterations in Chen or Siol in order to arrive at the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 6, 12-16, 18-23, 27-35 are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

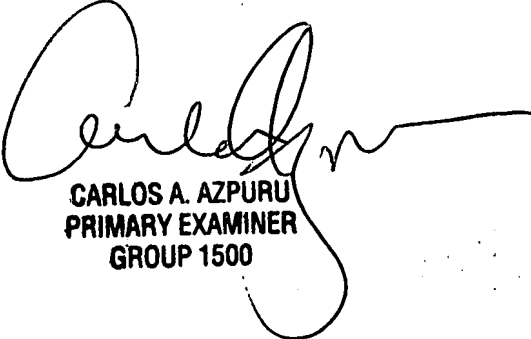
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

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Art Unit 1615



CARLOS A. AZPURU
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